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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,494	04/20/2004	Troy M. Walters	5490-000373	5234
27572 7590 11/25/2008 HARNES, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			EXAMINER ARAJ, MICHAEL J	
			ART UNIT 3775	PAPER NUMBER
			MAIL DATE 11/25/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,494	WALTERS ET AL.	
	Examiner	Art Unit	
	MICHAEL J. ARAJ	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-25, 27-34 and 48-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Romano (U.S. Patent No. 5,002,546).

Romano discloses a method of forming a non-linear tunnel through a bone structure comprising interconnecting a flexibly drill shaft (26) and a drill head (61); forming a small incision in a tissue near the bone structure; passing a drill head with the flexible drill shaft percutaneously through the small incision; drilling into the bone structure with the drill head at an entering position; guiding the drill head with the flexible drill shaft with a guide mechanism (68) along a selected non-linear cutting path within the bone structure; forming the selected non-linear cutting path with the drill head between the entering position into the bone structure and an exiting position out of the bone structure that is spaced a distance from the entering position in the bone structure; providing a suture near the exiting position; moving the drill head and the flexible drill shaft; engaging the suture with a suture mechanism near the drill head; and pulling the suture from the exiting position to the entering position with the suture mechanism. The guide mechanism includes a flexible rod at least partially enclosing at least a portion of the flexible drill shaft and having a proximal end and distal end where the flexible drill

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shaft is coupled to the flexible rod at the proximal end. The flexible member is interconnected with a distal end of the flexible drill shaft. Sliding of a handle to tension the flexible member moves the flexible member to engage the drill head. Romano also discusses the use of an arthroscope during similar arthroscopic surgeries (Col. 2, lines 53-66 and Col. 8, lines 38-52)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Romano (U.S. Patent No. 5,002,546)

Romano discloses the claimed invention except for the shaft or flexible rod being made of a memory shape alloy. It would have been obvious to one having ordinary skill in the art at the time the invention was made the devices of a memory shape alloy, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Romano (U.S. Patent No. 5,002,546) further in view of Hyde (U.S. Publication No. 2002/0095214).

Romano discloses the claimed invention except for being used on a humeral head. Hyde discloses forming a nonlinear tunnel through the head of the humerus (Fig. 2D) wherein the entry position is near at least one of a lateral side of the humerus, a superior side of the humeral head, or combinations thereof; and the exit position is at least one of the other of the lateral side of the humerus, the superior side of the humeral head, or combinations thereof. The path shown by Hyde can be performed by the device of Romano, for quicker treatment of the joint. It would have been obvious to one skilled in the art at the time the invention was made to have used the device of Romano on a humerus as taught by Hyde in order to reduce the amount of steps needed for this surgery.

Claims 39-45, 51 and 52 rejected under 35 U.S.C. 103(a) as being unpatentable over Romano (U.S. Patent No. 5,002,546) in view of Fukuda (U.S. Patent No. 4,345,601).

Romano discloses the claimed invention except for moving a suture engaging member near the drill head through the formed tunnel, pulling a suture through the formed tunnel in a second direction to pull the suture from the exit position to the entry position and engaging the bone structure with the suture. Fukuda discloses the lacking method in of Romano with tissue (Figures 9-13). Fukuda also discloses having the suture move in the same direction of the cutting head (Figures 1-4). These methods disclosed have an improved suture method for continuous suturing in less time. It would have been obvious to one skilled in the art at the time the invention was made to have created the device of Romano with a way to pull a suture through the formed tunnel in

view of Fukuda, in order to have a method of repairing a bone structure that was completed faster.

Claims 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Romano (U.S. Patent No. 5,002,546) in view of Fukuda (U.S. Patent No. 4,345,601) further in view of Hyde (U.S. Publication No. 2002/0095214).

Romano and Fukuda disclose the claimed invention except for being used on a humeral head. Hyde discloses forming a nonlinear tunnel through the head of the humerus (Fig. 2D) wherein the entry position is near at least one of a lateral side of the humerus, a superior side of the humeral head, or combinations thereof; and the exit position is at least one of the other of the lateral side of the humerus, the superior side of the humeral head, or combinations thereof. The path shown by Hyde can be performed by the device of Romano, for quicker treatment of the joint. It would have been obvious to one skilled in the art at the time the invention was made to have used the method of Romano and Fukuda on a humerus as taught by Hyde in order to reduce the amount of steps needed for this surgery.

Claims 39-41 and 43-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hariri et al. (U.S. Patent No. 6,328,744) further in view of Hyde (U.S. Publication No. 2002/0095214).

Hariri et al. disclose a method of forming a non-linear tunnel through a bone structure comprising interconnecting a flexibly drill shaft and a drill head; forming a small incision in a tissue near the bone structure; passing a drill head with the flexible drill shaft percutaneously through the small incision; drilling into the bone structure with the

drill head; guiding the drill head with the flexible drill shaft with a guide mechanism along a selected non-linear cutting path; forming the selected non-linear cutting path between an entering position and an exiting position spaced a distance from the entering position in the bone structure; providing a suture near the exiting position; moving the drill head and the flexible drill shaft; engaging the suture with a suture mechanism near the drill head; and pulling the suture from the exiting position to the entering position with the suture mechanism. The guide mechanism includes a flexible rod at least partially enclosing at least a portion of the flexible drill shaft and having a proximal end and a distal end where the flexible drill shaft is coupled to the flexible rod at the proximal end. The flexible member is interconnected with a distal end of the flexible drill shaft. Sliding of a handle to tension the flexible member moves the flexible member to engage the drill head (see Figures 17A-17D). Harari discloses the claimed invention except for being used on a humeral head. Hyde discloses forming a nonlinear tunnel through the head of the humerus (Fig. 2D) wherein the entry position is near at least one of a lateral side of the humerus, a superior side of the humeral head, or combinations thereof; and the exit position is at least one of the other of the lateral side of the humerus, the superior side of the humeral head, or combinations thereof. The path shown by Hyde can be performed by the device of Harari et al., for quicker treatment of the joint. It would have been obvious to one skilled in the art at the time the invention was made to have used the device of Harari et al. on a humerus as taught by Hyde in order to reduce the amount of steps needed for this surgery.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Harari et al. (U.S. Patent No. 6,328,744) in view of Hyde (U.S. Publication No. 2002/0095214) and further in view of Moore et al. (U.S. Patent No. 4,872,451).

The combination of Harari et al. and Hyde discloses the claimed invention except for positioning of an arthroscope. Moore et al. disclose the use of an arthroscope for visualization of a selected region (Col. 3, Paragraph 6). It would have been obvious to one skilled in the art at the time the invention was made to have the method of Harari et al. and Hyde with the use of an arthroscope in view of Moore et al., in order to better visualize the procedure.

Response to Arguments

Applicant's arguments with respect to claims 21-38 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for art cited of interest.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL J. ARAJ whose telephone number is (571)272-5963. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael J Araj/

Examiner, Art Unit 3733

EDWARD ROBERT
SUPERVISOR, PATENT EXAMINER